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72

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,341	08/13/2001	Barry M. Forman	1954-352	6094

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/927,341	<b>Applicant(s)</b> FORMAN ET AL.	
	<b>Examiner</b> Anne Holleran	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/21/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 94-111 is/are pending in the application.
- 4a) Of the above claim(s) 96-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 94,95 and 103-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I, claims 94, 95 and 103-111, in the response filed Oct. 21, 2003, is acknowledged. The traversal is on the ground(s) that it would not be an undue burden on the examiner to examine both Group I and group II. This is not found persuasive because the inventions of group II are drawn to products that are described functionally, and claimed by describing an inherent property, and it would only be fortuitous if an example of such compound were to be found during the search of the method claims. A complete search of the invention group II is not coextensive with a search of invention group I, because the search for the products of group II would require searching beyond the stated inherent properties of the claimed products.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 94-111 are pending.

Claims 96-102, drawn to non-elected inventions, are withdrawn from consideration.

Claims 94, 95 and 103-111 are examined on the merits.

3. Claims 94, 103, and 108 are objected to for containing abbreviations that have not been defined at the first instance in the claims. Correction is required.

***Claim Rejections - 35 USC § 112***

4. Claim 110 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 110 is indefinite because the method steps do not correlate with the state purpose of the method. As presently claimed, the method provides one with a set of compounds that inhibit the cellular production of p-glycoprotein, which is not the same thing as determining a compound that inhibits SXR transactivation of an SXR target gene.

5. Claims 94, 104-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the claimed methods are not adequately described by the specification as originally filed because the specification fails to describe the genus of SXR target genes, and fails to describe the genus of reporter genes that are regulated by the functional association of the ligand binding domain of SXR with an SXR coactivator.

The claimed methods require the step of determining whether a test compound inhibits SXR transactivation of an SXR target gene. Thus, the claimed methods require the use of a product that is a reporter construct of an SXR target gene. The specification only describes two examples of SXR target genes, the *mdr1* gene and the *cyp3a4* gene. These two genes are not representative of the genus of all SXR target genes that are yet to be discovered, and the

Art Unit: 1642

description of these two genes is not adequate to describe the entire genus or to demonstrate that applicant was in possession of the entire genus. Mere contemplation of the genus is not adequate to demonstrate possession, because the two exemplified genes are different in structure and function, and the specification has not described a common structural feature of the genus. Therefore, one of skill in the art would not understand that applicant was in possession of the claimed inventions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 110 is rejected under 35 U.S.C. 102(e) as being anticipated by Shtil (U.S. Patent 6,71,786; issued Jan. 9, 2001; effective filing date June 7, 1996).

Claim 110 is drawn to method of determining whether a compound inhibits SXR tans activation of an SXR target gene comprising determining whether the amount of p-glycoprotein decrease with the addition of the test compound. It is noted that the method steps do not appear to correlate with the preamble, because it is not clear from the specification that all agents that may decrease p-glycoprotein will be agents that do so via inhibition of the SXR transactivation of the *mdr1* gene (or any SXR target gene).

Art Unit: 1642

Shtil teaches a method of discovering agents that inhibit the expression of the *mdr1* gene (col. 12, line 11 – col. 18, line 19). Thus, Shtil teaches a method that is the same as that claimed.

***Conclusion***


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
January 12, 2004

  
ANTHONY G. CAPUTA  
CURRENTLY PATENT EXAMINER  
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